Six Month Abstinence Heterogeneity in the Best Quit Study

Harold S. Javitz, PhD^{1,✉} • Terry M. Bush, PhD² • Jennifer C. Lovejoy, PhD³ • Alula J. Torres, MPH² • Tallie Wetzel, BA¹ • Ken P. Wassum, BA² • Marcia M. Tan, PhD⁴ • Nabil Alshurafa, PhD⁴ • Bonnie Spring, PhD⁴

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Abstract

Background Understanding the characteristics of smokers who are successful in quitting may help to increase smoking cessation rates.

Purpose To examine heterogeneity in cessation outcome at 6 months following smoking cessation behavioral counseling with or without weight management counseling.

Methods 2,540 smokers were recruited from a large quitline provider and then randomized to receive proactive smoking cessation behavioral counseling without or with two versions of weight management counseling. A Classification and Regression Tree (CART) analysis was conducted to identify the individual pretreatment and treatment characteristics of groups of smokers with different quitting success (as measured by point prevalence of self-reported smoking of any amount at 6 months).

Results CART analysis identified 10 subgroups ranging from 25.5% to 70.2% abstinent. The splits in the CART tree involved: the total number of counseling and control calls received, whether a smoking cessation pharmacotherapy was used, and baseline measures of cigarettes per day, confidence in quitting, expectation that the study would help the participant quit smoking, the motivation to quit, exercise minutes per week, anxiety,

and lack of interest or pleasure in doing things. Costs per quitter ranged from a low of \$US270 to a high of \$US630. Specific treatment recommendations are made for each group.

Conclusions These results indicate the presence of a substantial variation in abstinence following treatment, and that the total extent of contact via counseling calls of any type and baseline characteristics, rather than assigned treatment, were most important to subgroup membership and abstinence. Tailored treatments to subgroups who are at high risk for smoking following a quit attempt could increase successful smoking cessation.

Keywords CART • Smoking cessation • Weight management • Cost per quitter • Intentions • Abstinence • Relapse

Introduction

Research shows that two-thirds of smokers calling quitlines are overweight or obese, and two-thirds are concerned that quitting smoking will cause them to gain weight [1]. Understanding how to optimize both smoking cessation and weight gain reduction in the quitline setting is an important public health priority. Several previous studies have been conducted to determine the impact on tobacco abstinence and suppression of excess weight gain of adding weight management intervention to tobacco cessation counseling [2–4]. Those studies motivated the clinical study (the Best Quit Study or BQS) [5], providing data for this analysis. Here, we address the cessation outcomes of that study.

The BQS study tested the impact on abstinence and weight control of adding an evidence-based weight control intervention simultaneously with or sequentially after cessation treatment delivered via telephone quitlines. Results of the randomized controlled trial

✉ Harold Javitz
harold.javitz@sri.com

¹ Education Division, SRI International, 333 Ravenswood Ave., Menlo Park, CA 94025, USA

² Optum Center for Wellbeing Research, Optum, Seattle, WA 98104-1139, USA

³ Optum Center for Wellbeing Research, Arivale, Inc and Institute for Systems Biology, Seattle, WA, USA

⁴ Department of Preventive Medicine, Feinberg School of Medicine, Northwestern University, Chicago, IL, USA

indicated that multiply imputed abstinence rates were lower for simultaneous (40.3%) than sequential (48.3%) and control (44.9%) participants at 6 months ($p < .05$) and 12 months (40.7% versus 46.3% and 46.0%, respectively, $p < .05$). However, completers showed no differences in abstinence at 6 or 12 months. Observed and multiply imputed weight gain at 6 and 12 months was minimal and not different among treatment groups [5]. The treatments showed limited average weight management effects, at least partly because individuals assigned to each treatment group differed substantially in their outcomes. The goal of the current paper is to identify characteristics of smokers who have low cessation rates at 6 months (the time period closest to the treatments received) and to compare their baseline and treatment characteristics with those who are successful at quitting. This can improve our understanding of predictors of the heterogeneity of quit outcomes and help identify groups who may need additional or different support with quitting.

Methods

Recruitment, Screening, and Randomization

The Best Quit intervention study is described in detail by Bush et al. [5–7] and summarized below. This study was implemented by Alere Wellbeing, a provider of tobacco quitline services and a phone/web-based weight management program. Participants were recruited from three state quitlines and 10 commercial (workplace) quitlines. Candidates were eligible if they were 18 years of age and older, had a body mass index (BMI) ≥ 18.5 , smoked at least 10 cigarettes per day (CPD), wanted to quit smoking within 30 days, and could speak and read English. A total of 2,528 individuals were found eligible and randomly allocated to one of three treatment groups (cessation alone, simultaneous weight management, or sequential weight management). Process and outcome data at 6 and 12 months were collected via web survey, phone, and mail.

Intervention and Control Arm Procedures

Smokers in all study arms received 10 coaching calls plus additional calls if requested. Coaches made several attempts per day over five different days to reach study participants to complete each of their 10 planned counseling sessions. Treatment was participant focused, so the duration of each call varied by participant needs but followed the general protocol of 20 min for Call 1 and 10 min for remaining calls. The first “inbound” call was initiated by the smoker; “proactive” calls 2–10 were initiated by the

coach. All participants could phone in to the quitline for additional support at any time. The cessation-only treatment group (control) received five standard quitline cessation calls followed by five healthy living program calls. The simultaneous group received five calls that combined cessation and weight management content followed by five healthy living program calls. The sequential group received five standard quitline cessation calls followed by five weight management calls. The healthy living calls acted as a contact control to equalize number of contacts with a coach across all three groups. For the simultaneous group, during the second call, a quitline coach completed the standard tobacco content and then transferred the participant to a registered dietician (RD).

Tobacco Cessation Treatment

The cessation treatment for all groups involved the Quit for Life (QFL) program that includes five telephone counseling sessions with a coach plus unlimited call-ins to the quitline for help at any time, a website with support materials, a mailed Quit Kit, and free nicotine replacement therapy (NRT) in the form of patch, gum, and/or lozenge (0–8 weeks) depending on the contract for providing smoking cessation services and appropriateness based on the participant’s medical condition.

Weight Management Treatment

The weight management program for the simultaneous and sequential treatment groups involved five counseling calls offered by coaches and RDs, mailed materials, and access to a web-based weight management program with on-line tracking forms, goal setting, and educational components. Coaches encouraged participants to set diet, physical activity, and weight goals, regularly self-monitor their weight, dietary intake (e.g., calories), stress, and physical activity level. The second call of the weight management intervention (Call 2 for simultaneous, Call 8 for sequential) was delivered by an RD and covered calorie reduction strategies and the rationale for why and how to reduce caloric intake. Dietary, physical activity, and behavior change intervention content came from interventions proven to be efficacious in producing weight loss [8–11]. The physical activity component focused on moving more and sitting less. A stress reduction component focused on identifying and controlling stressful situations, finding and practicing coping skills, and monitoring progress.

Healthy Living Program Calls

The five healthy living (control) calls addressed sun protection, flu prevention, pedestrian safety, disaster preparedness, and home energy savings. During these calls, coaches did not discuss tobacco or weight.

Coaches

Interventions were delivered by experienced coaches and RDs. Coach training included reviewing the treatment manual, listening to tape recorded “mock” calls and practicing the intervention content via role-plays. Coaches covered specific intervention topics visible to them via their on-line coaching application.

Data Collection

Participants’ demographic, smoking, and weight characteristics were assessed by self-report surveys administered at baseline by a quitline registration agent and a coach (depending on the item being assessed) and at 6 and 12 months postrandomization by the survey team who were blinded to treatment arm. Participants could earn up to \$110 for completing the three surveys (\$30 for baseline; \$35 for the 6 month survey, \$35 for the 12 month survey, and \$10 for early completion of the 12 month web survey). Two weeks prior to the 6 and 12 month target dates, participants were sent an email with a link to the survey. Survey nonresponders were sent reminder emails and those still nonresponsive were contacted by phone. Survey staff attempted telephone outreach for at least 11 days and left several voice messages asking the participant to call the quitline. Individuals who still did not respond were sent a mailed copy of the survey with a stamped return envelope. Those who failed to return the mailed survey within 2 weeks were sent a short form survey asking only four questions (satisfaction, tobacco status, CPD, and current weight). The envelope stated that compensation was enclosed (a \$2 bill was enclosed with the survey). In addition to self-reported data, call completion data were collected by Alere and included type and number of counseling calls completed (scheduled and participant-initiated calls).

Study Measures

Screening data collected by a registration agent when a smoker called into the quitline included standard demographic and tobacco use questions (e.g., name/address/phone numbers, self-reported age, gender, and chronic disease status [asthma, pulmonary disease, heart disease, or diabetes] plus study-specific questions (CPD, height, weight, history of eating disorder, weight loss surgery, access to internet; reachable for next 6 months; and willing to take additional five counseling calls). Baseline data collected by a coach prior to randomization included questions about race, ethnicity, education, marital status, depression/anxiety, whether dieting, level of concern about weight gains after quitting, and confidence about avoiding weight gain while staying quit. Content of the

6 month and 12 month surveys included self-reported: duration of “no puff” abstinence, type and amount of tobacco used, cessation medications used, symptoms of depression or anxiety, satisfaction with the quitline, satisfaction with the study, current weight, changes in diet, eating patterns, physical activity level, and use of an activity monitor. A subset of these measures was used for the current paper.

The measures used for this paper are in line with the theoretical underpinnings of the study interventions and have been shown to be related to treatment outcomes. In accordance with the treatment model (social cognitive theory) used for this study, treatment focused on personal, environmental, social, and behavioral factors, which influence each other in ways shown to change health behavior [12]. Within this theoretical model are concepts that have an effect on motivation and predict cessation and/or weight outcomes including: anticipated outcomes of a behavior (expectations) [4, 13] and confidence in one’s ability to take action (self-efficacy) [12]. Specifically, we included variables known to predict health behaviors of tobacco cessation and /or weight control. These include personal factors such as lower age, lower education, and socio-economic status, being male, greater nicotine dependence measured by CPD, and weight-related factors (BMI, weight concerns, dieting behaviors). Motivation for quitting tobacco [14] and self-efficacy for smoking abstinence and confidence in avoiding weight gain are also predictive of health behavior changes [15–17].

Statistical Analysis

CART analysis was used to separate individuals into groups that exhibited different 6 month observed abstinence. CART is a form of decision tree learning commonly used in data mining [18]. CART recursively splits participants into subgroups based on a collection of variables that potentially predict the outcome of interest (which in this study is abstinence at 6 months). Predictors are selected based on their ability to optimally divide patients into smaller homogeneous subgroups, with each split improving homogeneity [19]. CART creates trees that are easy for clinicians to interpret [20, 21]. It is particularly useful in identifying subgroups of individuals because it: (a) does not assume that predictors are linearly related to the outcome of interest; (b) examines all possible cut-points across all predictors at each split; (c) examines all possible interactions among predictors; and (d) is able to compensate for missing predictor values without the need for imputation [19, 21]. It has been widely used to identify subgroups of individuals who have positive or negative results from treatment [22–26]. Unlike most clustering approaches to identifying “hidden” subgroups

of the data, CART attempts to form subgroups that are homogeneous with respect to a particular target measure.

CART is a machine-learning method for constructing prediction models from data, which can be represented graphically as a tree [27]. In the current study, the end nodes are groups which have different 6 month observed abstinence rates. The CART tree is obtained by recursively partitioning data by identifying a predictor of 6 month observed abstinence and by splitting the data on a value of that predictor into “left” and “right” branches. Prediction error is measured in terms of misclassification rate or cost (if there are different costs associated with different types of misclassification). In this study, CART was implemented using the R package RPART [28]. Receiver operating characteristic (ROC) analysis was used to calculate the ROC area under the curve (AUC) of the groups. AUC is a measure of the diagnostic ability of a binary classifier as its discrimination threshold is varied (where such variation alters the sensitivity and specificity of the classifier) [29]. AUC is a general method for assessing any binary classifier. The AUC was validated using fivefold cross validation. Cross validation involved randomly dividing the set of respondents into five subsets, using one subset (containing 80% of all observations) to estimate the algorithm for determining end nodes and the complementary subset (of 20% of all observations) to assess the percentage correctly classified by those end nodes. This was repeated five times with the complementary subsets being nonoverlapping.

Table 1 displays the variables from the regression, baseline, and 6 month surveys and call completion data that were used in the CART analysis to predict observed 30 day abstinence at 6 months, with the restriction that each end node contains 50 or more individuals. We chose 50 individuals because in our experience, smaller nodes are insufficiently stable and we wanted a large enough proportion of participants per node to justify the effort involved in formulating and implementing a tailored treatment. The 6 month variables reflected use of pharmacotherapies anytime from baseline and weight change from baseline to 6 months.

The predictive ability of the CART tree was assessed using three separate approaches. First, a logistic regression was performed where the dependent variable was abstinence at 6 months and the independent variable was a categorical variable denoting the different end nodes to establish that the groups were statistically significant predictors of abstinence. Second, a logistic regression [30] was conducted at each point at which a branch split to assess the statistical significance of that split. Third, the percentage of correct classifications and AUC [31] was calculated for all observations and using fivefold cross validation [32] to assess the extent to which the identified groups improved the assessment of abstinence. In

addition, separate logistic or linear regressions were conducted for each of the predictor variable as the dependent variable and a categorical variable denoting the end nodes as the independent variable to screen the predictors prior to examining them to determine whether there were potentially clinically important differences between the groups with respect to those predictors.

Cost Effectiveness Analysis

Cost per quitter was calculated for the purpose of determining groups where changes in treatment might lead to reduced costs by increasing the percentage quitting enough to compensate for the costs of additional treatment. To determine the cost per quitter at 6 months, the costs for various treatment components were estimated, excluding any costs that were only associated with research activities. Labor costs for call minutes were calculated using an average wage of \$27.84 per hour for a health educator (occupational code 21–1091 in May 2016 from BLS.gov) to which was added 25% for benefits. Call attempts were costed at \$1.53 each, letters sent at \$0.49 each, voicemails at \$3.06 each, QFL materials at \$4.16 per enrollee, and Weight Talk materials at \$8.67 per enrollee. Medications were costed at \$18.79 per week of use, obtained by averaging costs from Costco, Walmart, and Amazon for 14 or 21 day NRT packages. We assumed the following: (a) 2 weeks of medication use for enrollees who were not part of an employer’s program; (b) 4 weeks of medication use for enrollees who were part of an employer’s program with Optum and who stated that they had used medication and were not abstinent at 6 months; and (c) 8 weeks of medication use for enrollees who were part of an employer’s program with Optum and who stated that they had used medication and were abstinent at 6 months. The largest cost components were call attempts, call minutes, and medications, followed by voicemails. QFL materials, Weight Talk materials, and letters were relatively minor expenses. While costs per enrollee were comparable across groups, costs per abstainer varied by a factor of more than 2 (\$270 to \$629 per abstainer).

Results

CART Tree

Figure 1 contains the CART tree for 30 day observed abstinence at 6 months. The tree contains 10 end nodes, defined by various splitting variables such as quit confidence. Each end node contains the following information: (a) the number of observations in that end node, (b) the number of those observations that were either

Table 1 Variables used in CART analysis as predictors (independent variables)

	Source	Variable name, description, and coding
1	Registration	Age (years), height (feet and inches), weight (lbs), BMI (calculated)
2	Registration	Female (coded as 1 = Female, 0 = Other/Missing)
3	Registration	Asthma, coronary artery disease (CAD), chronic obstructive pulmonary disease (COPD), diabetes (each coded as 1 = Yes, 0 = No)
4	Registration	NoChronic. None of 4 listed chronic conditions (coded as 1 = none of asthma, CAD, COPD or diabetes; 0 = at least one of asthma, CAD, COPD, and/or diabetes)
5	Registration	CPD. Cigarettes per day (count)
6	Baseline	Race (coded as 1 = White, 2 = Black or African American, 3 = Other)
7	Baseline	Hispanic (1 = Yes, 0 = No)
8	Baseline	Education (coded as 1 = <9th grade, 2 = 9–11, HS degree, 3 = some tech, tech/trade degree, 4 = some college, or 5 = college degree)
9	Baseline	Marital status (coded categorically as 1 = single, 2 = married or living together, 3 = separated, divorced, or widowed)
10	Baseline	Anxiety. Over the last 2 weeks, how often have you been bothered by feeling nervous, anxious, or on edge? (coded as 0 = not at all, 1 = several days, 2 = more than half the days, 3 = nearly every day)
11	Baseline	NoPleasure. Over the last 2 weeks, how often have you been bothered by little interest or pleasure in doing things? (coded as 0 = not at all, 1 = several days, 2 = more than half the days, 3 = nearly every day)
12	Baseline	Feeling down. Over the last 2 weeks, how often have you been bothered by feeling down, depressed or hopeless? (coded as 0 = not at all, 1 = several days, 2 = more than half the days, 3 = nearly every day)
13	Baseline	Worry. Over the last 2 weeks, how often have you been bothered by not being able to stop or control worrying? (coded as 0 = not at all, 1 = several days, 2 = more than half the days, 3 = nearly every day)
14	Baseline	ExerDays. Number of days of moderate to strenuous exercise in the last 7 days
15	Baseline	ExerMins. Exercise minutes per day (On those days that you engaged in moderate to strenuous exercise, how many minutes, on average, did you exercise at this level?)
16	Baseline	ExerTotMins. Calculated total number of exercise minutes per week.
17	Baseline	Dieting (coded as 1 = not currently dieting, 2 = dieting to lose weight, 3 = dieting to keep weight where it is right now)
18	Baseline	Medicaid. Medicaid medical insurance (coded as 1 = Yes, 0 = No)
19	Baseline	WgtGainLikelihood. How likely do you think it is that you will gain weight as a result of quitting/staying quit? (coded 1 = not at all likely, ..., 10 = extremely likely)
20	Baseline	Motiv. How motivated are you to quit? (coded 1 = low to 10 = high)
21	Baseline	QuitConf. How confident do you feel that you can quit? (coded 1 = not at all confident, ..., 10 = extremely confident)
22	Baseline	WgtGainConf. How confident are you that you can avoid gaining weight while staying quit? (coded 1 = not at all confident, ..., 10 = extremely confident)
23	Baseline	WgtGainConc. Concern about gaining weight as a result of quitting (coded 1 = not at all, ..., 10 = extremely concerned)
24	Baseline	HelpQuit. Thinking about your study group, please rate the degree to which you feel the program will help you quit smoking. (1 = not at all likely, ..., 10 = very high)
25	6 month	DrugCount. Number of pharmacotherapies used, selected from a list including NRT, nicotine gum, nicotine spray, etc.
26	6 month	M6_Wgt. Weight at 6 months (lbs)
27	6 month	M6_WgtGain. Weight change from baseline to 6 months (calculated)
28	Internal System	CommContract. Participant is covered by a commercial contract for smoking cessation services (coded 1 = Yes, 0 = No)
29	Calls	TotTobCalls. Number of completed tobacco calls (count of any planned or ad hoc call that discussed tobacco, including calls that discussed both tobacco and weight in the simultaneous group)
30	Calls	TotWgtCalls. Number of completed weight management calls (count of any planned or ad hoc call that discussed weight, including calls that discussed both tobacco and weight)
31	Calls	TotTobWgtCalls. Number of completed calls that discussed both tobacco and weight management
32	Calls	TotControlCalls. Number of completed healthy living calls
33	Calls	TotCalls. Total number of completed calls. This measure included tobacco or weight calls initiated by the participant and healthy living calls. Calls that discussed both tobacco and weight were counted as two completed calls.
34	Calls	TotActiveCalls. Total number of completed calls excluding healthy living calls.
35	Group	Group. Randomization group (coded as 1 = control, 2 = sequential, or 3 = simultaneous)

NRT nicotine replacement therapy.

Fig. 1. CART tree for 30 day observed abstinence at 6 months.

abstinent or relapsed (excluding missing values), and (c) the fraction of nonmissing values for 30 day abstinence that were abstinent. Out of a total of 2,528 observations in the tree, 1,106 have values for 30 day abstinence. The tree also contains the names of the splitting variables. Ten groups of participants were identified and shown as Groups A–J. The values defining the splits, the expected direction for abstainers, and the *p*-values for each split are presented in [Tables 2](#).

All of these splits were in the expected direction, with the exception of more exercise minutes per week being associated with lower abstinence. Closer examination of the two groups involved in the split on total exercise minutes suggests that the reason for this is that the group with fewer exercise minutes per week has a higher prevalence of chronic diseases and generally poorer health. This split differentiates Group D from E. Even though these two groups have equal stated high motivation to quit, the reasons behind that motivation differ (i.e., one motivated by poor health and the need to quit and the other by the desire for a healthy lifestyle) and this appears to result in different abstinence rates.

Statistical Significance

The logistic regression for the CART tree as a whole (i.e., where the dependent variable is 30 day observed abstinence at 6 months and the independent variable is a categorical variable denoting the end nodes) was statistically significant at $p < .001$ (chi-squared [9] = 134.3). The *p*-values for logistic regression at each split of the tree are shown in [Table 2](#). They are all less than .05, and, with one exception, are all less than .004. To correct for multiple testing, we also calculated the false discovery rates [33] and found them all to be <0.05 . The percentage classified correctly using the tree was 66.4% without cross validation

and 61.5% with fivefold cross validation. Cross validation involved randomly dividing the set of respondents into five subsets, using one subset (containing 80% of all observations) to estimate the algorithm for determining end nodes and the complementary subset (of 20% of all observations) to assess the percentage correctly classified by those end nodes. This was repeated five times with the complementary subsets being nonoverlapping. The AUC without cross validation was 0.662 with a 95% confidence interval (CI) of 0.634 to 0.689. With cross validation, the AUC was 0.615 with a 95% CI of 0.581 to 0.648. Sensitivity (percentage correctly classified among nonabstainers) and specificity (percentage correctly classified among abstainers) were, respectively, 58.7% and 73.6% without cross classification and 57.0% and 65.6% with cross validation.

Summary of Differences Between Groups by Characteristics

[Tables 3](#) shows differences between groups on predictor variables passing a screen requiring a statistically significant difference between groups. The table also contains response rate and abstinence variables that were statistically significantly different between groups. Predictors, response, and abstinence variables are clustered into logical groups, and for each variable, [Tables 3](#) also shows the average response across all respondents and (if applicable) the odds ratio of that variable with 6 month observed abstinence. Values in the table that are in bold type face (italic type face) are sufficiently above (below) the average to be potentially clinically interesting. There was no difference between groups in changes in weight or BMI. [Table 4](#) shows treatment costs.

Table 2 CART tree splitting information

Splitting variable	Row with definition in Table 1	Values to left	Values to right	Expected direction for abstainers	<i>p</i> -value *
QuitConf	21	<7.5	≥7.5	Right	<.001
HelpQuit	24	<6.5	≥6.5	Right	.001
DrugCount	25	<0.5	≥0.5	Right	.004
Anxiety	10	≥2.5	<2.5	Right	.001
ExerTotMins	16	≥37.5	<37.5	Left	.043
TotCalls	33	<6.5	≥6.5	Right	<.001
Motiv	20	<8.5	≥8.5	Right	<.001
CPD	5	≥19.5	<19.5	Left	.004
NoPleasure	11	≥1.5	<1.5	Right	.003

CPD cigarettes per day.

*The corresponding false discovery rate *q*-values are all less than 1% except for ExerTotMins, which is less than 5%.

Summary by Group

Below we summarize characteristics by group and specific tailored treatment recommendations:

Group A had below average abstinence rates across all 6 and 12 month abstinence measures. Their distinguishing characteristics are low confidence that they can quit or avoid weight gain, low motivation to quit, low expectation that the BQS group will help them to quit, below average exercise, below average percentage Black, above average commercial contract prevalence, and the highest cost per abstainer. Participants in this group may need treatment tailored to build their confidence in quitting, such as practicing quitting, celebrating successful mini-quits, and eliciting compelling reasons for quitting to increase their motivation. Encouraging these participants to increase their physical activity may help them overcome urges and symptoms of nicotine withdrawal.

Group B had below average 30 day observed abstinence rates but above average response rates, leading to average missing coded as relapser (MCR) abstinence rates. Their distinguishing characteristics are their lower than average prevalence and use of cessation pharmacotherapy at 6 months, racial makeup (higher percentage White and lower percentage Black), below average confidence that they can quit or avoid weight gain, below average weight and BMI, and low commercial contract and Medicaid prevalence. This group had low cost per enrollee (due to lack of medication) but above average costs per abstainer (due to low abstinence rates). Tailored treatment around medication adherence and the importance of using cessation medications and taking all coaching calls could help boost the quit rates in this group. This group may need more help identifying and addressing barriers to using NRT. Focusing on ways to increase confidence in quitting by experimenting with mini-quits and breaking the smoking cycle may help.

Group C had below average abstinence rates across all 6 and 12 month abstinence measures. Their distinguishing characteristics are above average use of cessation pharmacotherapy at 6 months, above average BMI, percentage female, percentage White, frequency of negative affect (worry, anxiety, lack of pleasure, and feeling down), Medicaid insurance, chronic obstructive pulmonary disease (COPD), presence of any of four chronic diseases, and below average percentage Black, confidence in ability to quit, commercial contract prevalence, and above average cost per abstainer. Members of this group may need more help to identify ways to increase their confidence (see above).

Group D had average abstinence rates across all 6 and 12 month abstinence measures. Their distinguishing characteristics are above average cessation pharmacotherapy prevalence and use, commercial contract prevalence, and exercise (days per week, minutes per day, and minutes per week) and below average age, percentage female, confidence that they can quit, frequency of negative affect (worry, anxiety, lack of pleasure, and feeling down), prevalence of Medicaid insurance, and prevalence of COPD or of any of four chronic conditions. This would appear to be a relatively physically and mentally healthy, young, and employed group. The costs per abstainer are about average. The quitline appears to be meeting the needs of this population.

Group E had above average 30 day observed abstinence at 6 months but was about average on the other abstinence measures. Their distinguishing characteristics were above average cessation pharmacotherapy prevalence and use and below average confidence in quitting or avoiding weight gain, negative affect measures (worry, anxiety, and lack of pleasure), and extremely low exercise (days per week, hours per day, and minutes per week). This may be a group with medical problems other than COPD, coronary artery disease, diabetes or asthma, which limit their exercise and result in generally

Table 3 Heterogeneity in predictor and abstinence outcomes across groups^a

Characteristic description (study-wide average, odds ratio [OR] with 30 day abstinence at 6 months)	Group designation									
	A	B	C	D	E	F	G	H	I	J
Number of participants										
Number in group	249	64	168	162	250	258	171	522	367	317
Number with observed 6 month abstinence	115	55	69	69	99	99	59	145	131	265
Response rate and abstinence										
Response rate at 6 months (43.8%)	46.2%	85.9%	41.1%	42.6%	39.6%	39.4%	34.5%	27.8%	35.7%	83.6%
Response rate at 12 months (57.8%, 1.14)	57.8%	71.9%	58.3%	58.6%	55.2%	51.9%	46.8%	51.5%	53.7%	82.3%
30 day observed abstinence at 6 months (51.4%)	27.8%	25.5%	30.4%	43.5%	63.6%	35.4%	30.5%	57.2%	65.6%	70.2%
30 day MCR abstinence at 6 months (22.5%)	12.9%	21.9%	12.5%	18.5%	25.2%	13.6%	10.5%	15.9%	23.4%	58.7%
30 day observed abstinence at 12 months (45.7%, 21.4***)	26.8%	32.6%	27.6%	43.1%	46.4%	38.8%	40.0%	48.3%	50.8%	64.0%
30 day MCR abstinence at 12 months (26.4%, 11.7***)	16.1%	23.4%	16.1%	25.3%	25.6%	20.2%	18.7%	24.9%	27.2%	52.7%
90 day observed abstinence at 12 months (38.6%, 27.0***)	22.9%	30.4%	23.4%	34.7%	40.6%	27.6%	32.5%	40.1%	41.6%	58.2%
90 day MCR abstinence at 12 months (22.3%, 17.0***)	13.3%	21.9%	13.7%	20.4%	22.4%	14.3%	15.2%	20.7%	22.3%	47.9%
Treatment variables: pharmacotherapy use, call completion, and randomization group										
Any pharmacotherapy use at 6 months (79.9%, 1.86***)	76.5%	0.0%	100%	100%	100%	74.5%	80.0%	81.8%	81.1%	81.1%
Number of pharmacotherapies used at 6 months (1.09, 1.06)	1.14	0.00	1.35	1.43	1.44	0.93	1.03	1.14	1.07	1.05
Any pharmacotherapy use at 12 months (73.9%, 0.82)	76.6%	41.3%	77.7%	75.0%	76.7%	76.3%	68.5%	73.5%	75.5%	74.5%
Number of pharmacotherapies used at 12 months (1.03, 0.78**)	1.13	0.67	1.00	1.07	1.18	1.02	0.97	1.04	1.05	0.96
Total calls (3.91, 1.09***)	4.13	3.95	3.59	4.36	4.19	2.42	2.40	2.52	2.80	9.05
Total active calls (3.82, 1.07***)	3.90	4.20	3.76	4.17	4.05	2.78	2.64	2.86	3.04	7.34
Total tobacco calls (2.73, 1.16***)	2.85	2.64	2.51	2.91	2.84	2.05	2.03	2.17	2.34	4.91
Total weight calls (1.09, 1.05)	1.05	1.56	1.24	1.26	1.21	0.73	0.61	0.69	0.70	2.43
Total combined tobacco and weight calls (0.62, 0.99)	0.58	0.83	0.73	0.61	0.60	0.50	0.47	0.48	0.45	1.17
Total control calls (0.79, 1.10**)	0.86	0.67	0.67	0.89	0.84	0.20	0.28	0.21	0.26	3.07
Control group ^b (33.2%, 1.09)	36.1%	20.3%	30.4%	33.3%	33.2%	32.9%	29.2%	32.2%	30.8%	41.9%
Demographics (age, BMI, weight, female gender, White and Black race)										
Age (43.2 years, 1.0)	42.9	41.6	41.4	39.3	43.5	41.0	45.0	43.1	43.2	47.8
BMI at baseline (30.0, 1.0)	29.3	27.8	31.0	29.5	30.5	31.1	29.7	29.4	29.6	30.8
Weight at baseline (189.1, 1.0)	186.4	179.2	189.7	192.4	190.9	198.0	187.3	186.1	185.5	192.5
Percentage female (65.8%, 0.92)	63.1%	65.6%	74.4%	57.4%	69.6%	60.5%	66.1%	64.8%	69.8%	66.2%
Percentage White (67.5%, 0.80)	76.3%	84.3%	80.4%	74.1%	68.4%	69.0%	66.7%	69.2%	52.9%	59.9%
Percentage Black (26.3%, 1.36*)	15.3%	9.4%	15.5%	20.3%	25.6%	24.0%	29.8%	24.5%	40.9%	34.1%
Confidence and motivation (confidence BQS will help quitting, quit confidence, weight avoidance confidence, motivation to quit)										
Expect BQS group will help quitting (8.36, 1.07***)	4.92	8.56	8.75	8.56	8.54	8.32	8.82	8.82	9.10	8.94
Confidence that can quit (7.85, 1.20***)	5.20	5.42	5.34	5.66	5.77	8.79	9.29	9.28	9.30	9.13

Table 3 Continued

Characteristic description (study-wide average, odds ratio [OR] with 30 day abstinence at 6 months)	Group designation									
	A	B	C	D	E	F	G	H	I	J
Confidence that can avoid weight gain (5.61, 1.06*)	4.88	4.69	5.08	5.45	4.95	5.61	5.98	6.00	6.15	5.88
Motivation to quit (8.92, 1.31***)	7.90	8.61	8.63	8.69	8.56	7.28	9.83	9.79	9.82	9.03
Negative affect (worry, anxiety, lack of pleasure, feeling down)										
Worry (in general) (1.25, 0.90)	1.27	1.39	2.34	0.83	1.06	1.17	1.87	1.04	1.22	1.08
Anxiety (in general) (1.29, 0.82***)	1.39	1.54	3.00	0.72	0.90	1.35	1.81	1.13	1.06	1.09
Lack of pleasure (0.91, 0.92)	0.89	1.15	1.41	0.66	0.79	0.98	2.55	0.36	0.85	0.86
Feeling down (0.78, 0.90)	0.95	1.14	1.50	0.53	0.60	0.81	1.33	0.54	0.67	0.65
Health (commercial contract, Medicaid, CPD, COPD, no chronic condition, exercise)										
Commercial contract (15.5%, 1.24)	20.1	9.4	8.3	20.1	14.4	12.0	7.0	15.5	16.3	21.8
Medicaid recipient (23.3%, 1.15)	19.7%	10.9%	34.5%	13.6%	23.6%	25.2%	28.1%	22.8%	23.7%	24.0%
CPD (20.0, 1.00)	20.3	20.1	20.3	19.0	19.6	20.0	25.7	24.6	12.2	19.2
COPD (14.5%, 0.72*)	12.4%	17.2%	22.6%	6.2%	14.8%	12.0%	21.8%	14.2%	12.0%	15.8%
COPD, diabetes, CHD, or asthma (40.9%, 0.95)	34.1%	39.1%	53.6%	31.5%	39.6%	38.4%	51.2%	41.0%	40.2%	42.6%
Exercise										
Exercise days per week (2.50, 1.05*)	1.92	1.97	2.21	3.93	1.45	2.37	2.83	2.71	2.88	2.54
Exercise minutes per day (54.3, 1.00)	33.4	55.8	54.2	127.8	10.8	58.5	54.4	55.8	58.2	53.6
Exercise minutes per week (248, 1.00)	139	281	249	558	38	269	267	262	268	250

BQS Best Quit Study, CHD coronary heart disease, COPD chronic obstructive pulmonary disease, CPD cigarettes per day, MCR missing coded as relapse.

* $p < .05$; ** $p < .01$; *** $p < .001$.

^aValues in bold type face (italic type face) are sufficiently above (below) average with respect to the row variable to be potentially important characteristic of the group.

^bThere were no statistically significant differences across groups in the proportion of sequential or simultaneous group members.

Table 4 Average costs per enrollee and per abstainer

Cost component	A	B	C	D	E	F	G	H	I	J
Call attempts (\$ per enrollee)	44.95	47.09	45.62	44.78	44.62	47.00	47.74	46.89	47.37	37.49
Letters (\$ per enrollee)	0.22	0.24	0.25	0.19	0.20	0.29	0.28	0.28	0.28	0.04
Voicemails (\$ per enrollee)	26.16	26.84	27.18	25.76	26.15	28.27	28.44	28.23	27.86	20.06
Call minutes (\$ per enrollee)	44.09	46.34	41.89	46.61	45.28	31.15	31.06	31.45	32.78	79.29
QFL materials (\$ per enrollee)	4.16	4.16	4.16	4.16	4.16	4.16	4.16	4.16	4.16	4.16
Weight Talk materials (\$ per enrollee)	5.54	6.91	6.04	5.78	5.79	5.81	6.13	5.88	6.00	5.03
Medications (\$ per enrollee)	49.78	0.00	54.16	71.35	71.71	44.23	42.04	54.40	58.39	63.91
Total costs (\$ per enrollee)	174.90	131.58	179.30	198.63	197.91	160.91	159.85	171.29	176.84	209.98
Abstinent rate at 6 months (%)	27.8	25.5	30.4	43.5	63.6	35.4	30.5	57.2	65.6	70.2
Total costs (\$ per 6 month abstainer)	629.14	516.00	589.80	456.62	311.18	454.55	524.10	299.46	269.57	299.12

QFL Quit for Life.

increased negative affect. Costs per abstainer were low. Providing a starter kit of pharmacotherapy appears to be helping participants to quit. Treatment recommendations include reinforcing the value of pharmacotherapy, encouraging continued use and providing suggestions for local sources of low-cost cessation medications. Discussing mini-quits or relapse prevention strategies may help boost participants' confidence in quitting and staying quit. Encouraging participants to increase their physical activity may help with their confidence in quitting without weight gain and improve or alleviate anxiety and negative affect.

Group F had below average 30 day abstinence at 6 months and below average 90 day abstinence at 12 months. Their distinguishing characteristics were below average call completion and motivation to quit and above average weight, BMI, and confidence that they could quit. Costs per abstainer were average. Tailoring treatment around medication adherence and the importance of taking all their counseling calls may be needed. Coaching on ways to boost their confidence and motivation could help members of this group.

Group G had below average 30 day observed and MCR abstinence at 6 months and below average MCR abstinence at 12 months. Their distinguishing characteristics were below average response rate at 12 months (which would have been a contributing factor to their low MCR abstinence rates at 12 months), call completion, and commercial contract prevalence and above average confidence and motivation to quit, worry, anxiety, lack of pleasure, frequency of feeling down, CPD, COPD prevalence, and prevalence of one or more of four chronic diseases. Costs per abstainer were above average due to large call minutes. Members of this group may benefit from tailored coaching about their depressive symptoms in relation to smoking and nicotine withdrawal and the importance of taking more coaching calls.

Group H had above average observed abstinence rates but below average 30 day MCR abstinence at 6 months (due to the low survey response rate at 12 months). Their distinguishing characteristics were below average call completion, low levels of worry, lack of pleasure, or frequency of feeling down and above average confidence and motivation to quit, and CPD. Costs per abstainer were below average. Tailored treatment around the importance of taking all counseling calls may be needed.

Group I had above average 30 day observed abstinence at 6 months. Their distinguishing characteristics were below average call completion, percentage White, and CPD and above average percentage Black, confidence and motivation to quit, and confidence in avoiding weight gain. Costs per abstainer were below average. While the quitline appears to be meeting the needs of this group, encouraging individuals to take all calls could boost their quitting skills.

Group J had above average abstinence across all measures and times. Their distinguishing characteristics were below average percentage White and above average call completion, percentage in the control group, percentage Black, confidence in quitting, and prevalence of commercial contracts. Costs per abstainer were below average. The quitline appears to be meeting the needs of this group.

Discussion

We identified 10 distinctive groups from the CART tree analysis based on 30 day observed abstinence at 6 months post intervention. Groups with low cessation rates had substantial differences from those with high cessation rates.

The majority of the variables that we examined as predictors either appeared in the CART tree or were statistically significant predictors of groups in an analysis of

variance. The only predictors that did not satisfy these criteria were Hispanic ethnicity, education, marital status, and whether the participants received weight management counseling. While BMI at baseline and confidence in avoiding weight gain while staying quit were statistically significant differentiators, other weight-related variables (amount of weight gain, self-assessed likelihood that the participant will gain weight as a result of quitting, dieting, and concern about gaining weight as a result of quitting) were not. This relative lack of weight-related variables (none of which are tree nodes) suggests that weight gain may be less important than other factors.

Study participants with low cessation rates (Groups A–C, F, and G) could be classified as having low confidence in quitting; low outcome expectancies that the quitline will help them to quit smoking; low use of cessation medications; more anxiety symptoms; and more physical activity. The group with low abstinence rates across all abstinence measures (Group A) was characterized by low confidence that they can quit or avoid weight gain, low motivation to quit, low expectation that the BQS group will help them to quit, below average exercise, and were less likely to be Black. The group that had one of the lowest cessation rates (Group B) was characterized by low confidence in quitting or avoiding weight gain similar to Group A, but this group also had low use of cessation medications, lower BMI, and a greater likelihood of being White. This group also had high rates of response to the 6 month survey and moderate engagement in counseling. Overall, smokers with low cessation rates may need more help boosting their confidence in quitting, more cessation medications (or combination pharmacotherapy such as nicotine patch plus gum or lozenge), and perhaps assistance with stress and anxiety. Tailored coaching around symptoms of nicotine withdrawal such as irritability and nervousness could be helpful.

Study participants with high 30 day cessation rates (Groups E, H–J) could be classified as having high confidence in quitting and high motivation to quit, and these cessation rates are similar. Among these groups, Group J has a substantially higher 90 day cessation rate. Group J is also characterized by high use of cessation medication and high call completion. Of the participants with high cessation rates, this group was the only group who completed more than the average number of calls (tobacco, weight, control, and total). All other groups had lower than average calls across all call types. Therefore, while confidence in quitting and motivation to quit appear sufficient to yield a high 30 day cessation rate, it appears that the addition of high use of cessation medication and treatment adherence (i.e., call completion) may be required to attain high 90 day abstinence.

In summary, confidence in being able to quit is an important variable, perhaps the most important. Why

are some people more confident than others? Perhaps they have tried quitting many times before and have come close and now believe they can push a little harder and succeed. Perhaps they are optimists. What can be done to improve confidence? We also note that the splitting variable in Fig. 1 after QuitConf is HelpQuit for individuals with lower confidence in their ability to quit and TotCalls for those with higher confidence. Quitline assistance appears to make a difference for people with low confidence, but if a person's confidence is already high, she also needs adherence (as measured by more total calls). If the person has high QuitConf but is not fully following through (TotCalls <6.5), it seems that motivation really matters, so working on motivation with the quit coaches would presumably be helpful.

Limitations

Study participants were smokers who were ready to quit and called state or commercial quitlines for help. The study sample might not be representative of smokers who have not sought cessation treatment or those using other forms of cessation support. However, participants were similar to the quitline population and, like the general quitline population, utilized only about half of the standard five-call tobacco cessation calls offered. The CART groups might have been different with greater overall call completion. Participant burden related to the number of proactive calls for treatment and to complete lengthy follow-up surveys may have impacted willingness to enroll in the study.

The CART classification tree was developed only on those individuals who responded to the 6 month survey, but the tree was applied to all study participants to examine the characteristics of the groups defined by the CART tree. Thus, there may be some differences between the group of individuals used to generate the CART tree (all of whom have values for abstinence at 6 months) and the individuals used to characterize the end nodes (some of whom do not have values for abstinence at 6 months). We considered developing the CART tree based on 30 day MCR abstinence at 6 months, but that would have relied on the false assumption that anyone without a 6 month questionnaire was a relapser, and the tree would be partially attempting to predict response rate rather than abstinence. In addition, there was a delay in mailing the 6 month questionnaire to some respondents, which may be partially responsible for individuals who did not respond in time (i.e., by the ninth month). We also considered restricting all analyses just to individuals who responded to the 6 month survey, but they would not be representative of the population, would eliminate our ability to calculate the response rate of each group, and would have reduced

the sample size for calculating abstinence at 12 months because there were many participants who did not respond at 6 months but did so at 12 months (as well as there being respondents at 6 months who did not respond at 12 months).

Another limitation is that data on smoking and weight were *self-reported without verification by direct objective measurement*. Although biochemical validation of smoking is ideal, self-reported smoking is consistent with standard measures used telephone-based interventions. Evidence suggests false reporting is minimal for low-intensity interventions with no face-to-face contact (the SRNT Subcommittee on Biochemical; An *et al.*). Regarding the use of self-reported weight, the literature indicates that people tend to consistently underestimate their weight and their weight gain across time points, with underestimation disproportionately greater among the more overweight/obese [34]. To address these problems, we asked participants their current weight at baseline and follow-up and use these data to calculate the weight gain using their self-reported weights. Studies have shown strong correlations between measured and self-reported weight indicating that self-reported weight is an “excellent approximation of actual weight across a population” [34–36]. In addition, all participants used self-reporting, so any biases in reporting should affect all CART groups about equally.

Despite potential limitations, this study addresses an important public health issue and provides new data concerning the characteristics that distinguish individuals with successful abstinence at 6 months from those with unsuccessful abstinence. This study shows that adding weight control to cessation treatment may adversely impact short-term quit rates when delivered concurrently with tobacco treatment via a reduction in call completion. This trial contributes to the science of tobacco treatment by describing groups with differential 6 month quit rates among smokers seeking treatment through a telephone tobacco quitline, two-thirds of whom also received weight management counseling (either simultaneous with or sequentially after smoking cessation counseling), and demonstrates the importance of testing efficacious treatments in population based settings.

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Compliance with Ethical Standards

Authors’ Statement of Conflict of Interest and Adherence to Ethical Standards Authors Harold S. Javitz, Jennifer C. Lovejoy, Tallie Wetzel, Ken P. Wassum, Marcia M. Tan, Nabil Alshurafa, and Bonnie Spring declare that they have no conflict of interest. Terry M. Bush and Alula J. Torres are employees of Optum which provides services for multiple quitlines in the U.S. The findings and conclusions of this paper do not necessarily reflect the views of Optum.

Authors’ Contributions H.S.J. served as the biostatistician for the trial. He collaborated on study design and implementation, led the analytic plans, data cleaning, analysis, and interpretation of the data and was the principal author of this manuscript. T.M.B., the PI, and B.S., Co-PI, conceptualized the study and obtained funding. T.M.B. provided oversight over all elements of the grant submission and implementation, and collaborated with authors on the design, methodology, implementation and dissemination of findings. B.S. worked with T.M.B., J.C.L., K.P.W. and H.S.J. to translate and implement her prior efficacy trial of a similar treatment to increase its population reach. B.S. collaborated on study protocols, developing the trial design and analytic protocol, collaborated on overseeing trial implementation, and reviewed all versions of the manuscript. J.C.L. co-developed the Weight Talk® intervention and worked with the study team to translate the more intensive program for delivery within a 5 call program. N.A. provided statistical consulting and reviewed all versions of the manuscript. A.J.T. acted as grant manager and oversaw protocol development, training and implementation and administrative tasks. As clinical director for the tobacco cessation quitline, K.P.W. provided oversight of the treatments, participated in study design, data analyses, interpretation of results and dissemination of the study. M.T. contributed to the interpretation of results and reviewed and provided edits to the revision of the manuscript. T.W. performed the statistical programming needed to implement CART.

Ethical Approval The Western Institutional Review Board and the State of Maryland Institutional Review Board—in accordance with the United States legislation—provided ethics approval and consent for the study.

Informed Consent Participant consent was obtained verbally via the phone and documented by trained staff. The tobacco cessation and weight management programs are overseen by a clinical team at Alere Wellbeing. All study participants were 18 years of age or older. Alere is a HIPAA covered entity and complies with all HIPAA regulations concerning ethics and informed consent.

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